

Morphine Sulfate Extended-Release Capsules

DEFINITION

Morphine Sulfate Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of morphine sulfate pentahydrate $[(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O]$.

IDENTIFICATION

- **A. INFRARED ABSORPTION** (197K)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Diluent: Water. Adjust with phosphoric acid to a pH of 3.6.

Buffer solution: 13.8 mg/mL of monobasic sodium phosphate

Solution A: Acetonitrile, triethylamine, *Buffer solution*, and water (25:0.5:100:874.5). Adjust with phosphoric acid to a pH of 3.6.

Solution B: Acetonitrile

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	100	0
33	100	0
44	85	15
54	85	15
55	100	0
65	100	0

System suitability solution: 400 µg/mL of USP Morphine Sulfate RS and 10 µg/mL of USP Morphine Related Compound A RS and 10 µg/mL of USP Morphine Related Compound B RS (pseudomorphine) in *Diluent*

Standard solution: 1.0 mg/mL of USP Morphine Sulfate RS in *Diluent*